DATE OUT: AUG 04 1994

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF:**
A MANUFACTURING-USE [ ] OR AN END-USE PRODUCT [X]
DP Barcode 203055 Reg. No. or File Symbol No. 63310-8

TO: Cynthia Giles-Parker/Clarence Lewis
PM Team No. 22

FROM: Sami Malak, Ph.D, Chemist, August 4, 1994
Product Chemistry Review Section
Registration Support Branch/RD (H7505W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (H7505W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

1. The submitted product chemistry data pertaining to the requirements of Series 63 Physical and Chemical Characteristics for this end-use product, Rhizopon-AA Water Soluble Tablets, Reg. No. 63310-8, is acceptable.

2. The submitted label for this end-use product, Rhizopon-AA Water Soluble Tablets, Reg. No. 63310-8, EPA received on 12/03/93, is acceptable.

3. The registrant will need to submit product chemistry data requirements of Series 61 and 62, as well as product CSF for this end-use product, Rhizopon-AA Water Soluble Tablets, Reg. No. 63310-8.

RECOMMENDATIONS

At this time, we are unable to recommend for reregistration of this end-use product, Rhizopon-AA Water Soluble Tablets, Reg. No. 63310-8, pending resolution of finding #3 above.

H7505W:RD:RSB:PCRS:CS-1:Rm650:S.Malak:s.m.:08-04-94:703-308-8392:63310-8.

PRODUCT CHEMISTRY REVIEW

MANUFACTURING-USE PRODUCT [ ] END-USE PRODUCT [X]

EPA Reg. No. (or File Symbol No.) 63310-8

Registration [ ] Reregistration [X]
Case No.: _____

DP Barcode/Chemist:

1) 203055/Sami Malak 3)

2) 4)

1. Product Name: Rhizopon-AA Water Soluble Tablets.

2. Company: 063310 Hortus USA Corporation

3. Type of Submission: New [ ] Resubmission [ ] Amendment [ ]
"ME-TOO" [ ] Alternate Formulation [ ] REPACK [ ]
Expt Use Permit [ ] Other (Specify) Old chemical

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4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered • yes [X] • no [ ]
- Integrated formulation system [ ]
- If "ME-TOO", specify EPA Reg. No. of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40CFR§180.1001:
• yes [ ] • no [ ]. If yes: • c[ ] • d[ ] • e [ ]
Cleared for non-food use: • yes [ ] • no [ ]

4c. Physical state of product: Solid

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes [ ] • no [ ]

4e. Density (or bulk density for solids): at °C.

4f. pH (if dissolved or dispersed in water):

4g. Flash point and/or flame extension:

4h. NCs and CLs are acceptable: • [ ] • not acceptable [ ]

4i.

Active ingredient(s)	NC	LCL	UCL
A. Indole-3-Butyric Acid.....	20.0		
B.			
C.			
D.			

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have an UCL: • yes [ ] • no [ ] • not applicable [ ]
- All impurities ≥ 0.1% in the product have been identified: • yes [ ] • no [ ] • not applicable [ ]

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5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [ ] • no [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: • yes [ ] • no [X]
- 1% or more of methyl alcohol: • yes [ ] • no [X]
- sodium nitrite at any level: • yes [ ] • no [X]
- a toxic List 1 inert at any level: • yes [ ] • no [X]
- arsenic in any form: • yes [ ] • no [X]

5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
• yes [ ] • no [ ] • not applicable [ ]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
• yes [ ] • no [ ] • not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses: • yes [X] • no [ ]

6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):
• yes [ ] • no [X]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/ Analytical Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix)[1]	G	
61-2a Manufacturing Process[2]	G	
61-2b Formulation Method[3]	G	
61-3 Discussion of Impurities[4]	G	
62-1 Analysis[5]	G	
62-2 Certified Limits[6]	G	
62-3 Analytical Method for AIs[7]	G	

6b. Physical/Chemical Properties	Accept of Data	Value or qualitat descrip[8]	MRID No.
63-3 Physical State	A	Solid	430330-01
63-7 Density/Bulk Density (gm/cc)	A	0.8 gm/cc	430330-01
63-12 pH of product [9]	A	6.3	430330-01
63-14 Oxid/Red Action	NA		
67-15a Flash Point(°C)[10]	NA		
63-15b Flame Extension	A	Non Flammable	430330-01
63-16 Explodability	A	Non Explosive	430330-01
63-17 Storage Stability (% degradation of AIs at 20-30°C for ≥ 1 year)	A	Stable	430330-01
63-18 Viscosity	NA		
63-19 Miscibility (with hydrocarbon solvents)[11]	NA		
63-20 Corrosivity (specify metals/conditions)	A	Non Corrosive	430330-01
63-21 Dielectric Breakdown Voltage[12]	NA		

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

Footnotes: [1] See Confidential Appendix A for additional information; [2] For MP/EP products produced by an integrated formulation system; [3] For products produced from a TGAI or MP; [4] May be waived unless actual/possible impurities are of tox concern; [5] Five batch analysis required for products produced by an integrated formulation system; [6] If different from standard CLs recommended in 40CFR§158.175, this should be discussed in Confidential Appendix A; [7] Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc. [8] Provide brief description, e.g., color - yellow or property value, e.g. density 1.25 g/cc. Unless otherwise indicated, the property should be at 25 C; [9] If product is a water solution or dispersion; [10] Not required for aerosols; [11] Emulsifiable liquids only; [12] For end-use products used near electrical equipment.

cc: Reviewer's Name and Central File (63310-8)
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